DOE REGULATORY PROCESS FOR RADIOLOGICAL, NUCLEAR, AND PROCESS SAFETY FOR TWRS PRIVATIZATION CONTRACTORS

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Preface

As noted below, the DOE regulatory approach for the radiological, nuclear, and process safety regulation of the TWRS Privatization Contractor is described in an integrated set of four documents, which should be read in the order listed below to obtain an understanding of the regulatory approach. The DOE regulatory approach to radiological, nuclear, and process safety clearly places on the Contractor the responsibility to achieve adequate safety, comply with applicable laws and legal requirements, and conform to top-level safety standards and principles stipulated by DOE. According to a prescribed process, DOE interacts with each Contractor in arriving at DOE decisions to approve and authorize Contractor activities. The DOE maintains a continuing interaction with the Contractor to ensure that the Contractor is meeting the safety conditions of its contract and the conditions of the DOE approvals; is complying with applicable laws and legal requirements; and is conforming to the DOE-stipulated top-level safety standards and principles.

Consistent with applicable laws and legal requirements, the requirements applied to each Contractor are tailored to control the hazards specific to the activities of that Contractor. With knowledge and understanding of the hazards specific to its activities, each Contractor is required to identify and recommend for DOE approval a set of safety standards to which the Contractor certifies, that when properly implemented, will ensure for that Contractor's activities 1) adequate safety, 2) compliance with applicable laws and legal requirements, and 3) conformance to DOE-stipulated top-level safety standards and principles. When DOE approves the set of Contractor-recommended safety standards, the set together with the DOE-stipulated top-level safety standards and principles becomes the requirements which are applied to the Contractor's activities.

The four documents that describe the DOE regulatory approach for the radiological, nuclear, and process safety regulation of TWRS Privatization Contractors are:

1. *Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0005; Revision 0,

2. *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0003; Revision 0,

3. *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006; Revision 0, and

4. *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization*, DOE/RL-96-0004; Revision 0.

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1.0 Purpose

The purpose of this document is to describe the process that the U.S. Department of Energy (DOE) will use to regulate the radiological, nuclear, and process safety of the TWRS Privatization Contractor (Contractor). This regulation will be achieved through a definitive and formalized process in which the Contractor obtains authorizations from DOE to undertake key safety-related actions. Once the bases for the authorizations are approved, authorization agreements will be negotiated between the DOE and the Contractor, and oversight by DOE will ensure that the Contractor's operations are in continued compliance with the agreements. This regulatory process is intended to be predictable, effective, unambiguous, compatible with the concept of privatization, and consistent with the regulatory concepts and principles of the Nuclear Regulatory Commission (NRC).

This document provides details of the six primary regulatory actions that are the essence of the regulatory process for the radiological, nuclear, and process safety regulation of TWRS Privatization Contractors. It specifies documentation required from the Contractor to support the six regulatory actions as well as specific activities by the DOE to accomplish each regulatory action, including review and approval schedules. The documentation requirements contained herein are considered by DOE to be generally complete in scope but flexible in the details of format and content in order to permit tailoring of the documentation to the nature and level of the hazards associated with the Contractor's activities. However, it is the Contractor's responsibility to ensure that within this flexibility all relevant information is provided to the Regulatory Unit that could materially affect the decisions and actions of the Director of the Regulatory Unit.

2.0. Scope

The regulatory process described herein applies only to the radiological, nuclear, and process safety regulation of the Contractor during Phase I of TWRS Privatization. While the scope of the regulation is predominantly limited to the Contractor's activities from initial design through deactivation, it also must include the Contractor's consideration of site characteristics, its use of site services, and its coordination with the DOE/RL's integrated emergency response

3.0 General Regulatory Structure

3.1 Regulatory Organization

The organization responsible for the radiological, nuclear, and process safety regulation of the Contractor is a specifically chartered, dedicated unit within DOE, designated the Regulatory Unit. The Regulatory Unit will function separately and distinctly from DOE, the customer. The Director of the Regulatory Unit will have the authority, on behalf of the DOE, to approve the Contractor's recommended safety standards and integrated safety management plan; to authorize construction, operation, and deactivation; to suspend operations; and to recommend enforcement actions. The Director of the Regulatory Unit will be responsible for

1) All regulatory interactions with the Contractor;

2) All safety reviews;

3) Safety review schedules;

4) Performing the regulatory functions in a disciplined and responsive manner;

5) Documentation of all regulatory actions and interactions;

6) Quality assurance of the regulatory functions;

7) All interactions with independent safety oversight organizations;

8) All safety regulatory interactions with the public; and

9) The protection of the Contractor's proprietary information, submitted.

The Director of the Regulatory Unit will formally issue all regulatory actions, such as approvals, authorizations, and corrective actions. The Director will also exercise approval authority on behalf of DOE for formally approving Contractor-generated items specified in the applicable regulations, as in 10 CFR 820, 10 CFR 830, 10 CFR 834, and 10 CFR 835.

The Regulatory Unit will use internally specified review procedures and acceptance criteria appropriate to the regulatory function. A full-time staff will manage and lead the reviews; will manage and lead the preparation of evaluation reports, recommendations for regulatory action, and authorization agreements; and will perform on-site inspections to support the regulatory oversight function. This full-time staff will be supported by on-call technical experts from other DOE organizations and support contractors, as appropriate.

3.2 Comprehensive Regulatory Process

The comprehensive regulatory process is shown in Figure 1 and consists of six regulatory actions. In approximate chronological order, these actions are

1) Standards Approval;

2) Initial Safety Evaluation;

3) Authorization for Construction;

4) Authorization for Production Operations;

5) Oversight Process Determination; and

6) Authorization for Deactivation.

This comprehensive regulatory process is intended to ensure that the Contractor's safety program achieves adequate radiological, nuclear, and process safety through requirements that are properly defined, implemented, and maintained. As indicated in the Figure 1, the Contractor and the Regulatory Unit will have an intensely interactive relationship during each of the periods of regulatory action.

An oversight function, independent from the Regulatory Unit, will also exist. This function will ensure that this regulatory process is implemented effectively and that its rigor is consistent with that expected from the NRC. This independent oversight function will be performed by the DOE Office of Environment, Safety, and Health.

3.3 Regulatory Actions

3.3.1 Standards Approval

The purpose of Standards Approval regulatory action is to approve the Contractor-recommended set of radiological, nuclear, and process safety standards and requirements documented in a Safety Requirements Document (SRD) and to approve the Contractor's standards-based integrated safety management program documented in an Integrated Safety Management Plan (ISMP). This action will provide assurance to the Contractor that its safety basis (safety technical approach and safety management practices) for the design and the projected construction, operation, and deactivation is adequate and acceptable, thereby providing a firm safety basis for a firm-fixed-price proposal for services to be provided in Part B of the contract.

The SRD shall include the Contractor's recommended standards for the format and content of information to be submitted by the Contractor for subsequent regulatory actions, and shall include standards for nuclear safety management features required by DOE regulations, particularly 10 CFR 830.

The ISMP shall include the planning elements of the implementation plans required by DOE regulations, particularly 10 CFR 830.

The approval of the Contractor's recommended set of radiological, nuclear, and process safety standards and requirements will be issued upon determination by the Director of the Regulatory Unit that:

1) The set documented in the SRD includes all requirements of applicable laws and regulations;

2) The set documented in the SRD conforms to the top-level radiological, nuclear, and process standards and principles contained in the DOE-provided document titled *Top-level Radiological, Nuclear, and Process Standards and Principles for TWRS Privatization Contractors,* DOE/RL-96-0006, Revision 0;

3) The hazards associated with the proposed facility and its operation are appropriately assessed;

4) The set documented in the SRD was generated through the appropriate implementation of the standards process stipulated by DOE in the document titled *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization,* DOE/RL-96-0004, Revision 0;

5) Appropriate expertise was employed in the standards selection and confirmation processes; and

6) The set documented in the SRD will provide adequate safety if properly implemented.

The approval of the Contractor's proposed ISMP will be issued upon determination by the Director of the Regulatory Unit that:

1) The program documented in the ISMP complies with all applicable laws and regulations;

2) The program documented in the ISMP conforms to the top-level radiological, nuclear, and process standards and principles contained in DOE/RL-96-0006;

3) The selected safety management processes documented in the ISMP are standards based and are appropriately tailored to the hazards associated with the Contractor's proposed facility, its operation, and its deactivation;

4) The selected safety management processes documented in the ISMP properly and adequately address management of process hazards;

5) The program documented in the ISMP contains appropriate features of integrated safety management (i.e., integration among safety, design, and operations interests; integration over the life cycle of the activities; and integration into work planning and performance);

6) The interfaces among regulatory regimes are appropriately addressed to ensure that adequate protection is fully achieved;

7) Safety documentation processes delineated in the ISMP provide for appropriate document control and maintenance;

8) Scheduling of the safety-related activities as described in the ISMP, including generation of regulatory submittals, is consistent with Figure 2 of this document;

9) Self assessment elements documented in the ISMP are appropriate; and

10) Safety definition, implementation, and maintenance roles, responsibilities, and authorities defined in the ISMP are clear and appropriate.

The approvals of the SRD and the ISMP will be based on the information provided by the Contractor (SRD, ISMP, and supplemental information described in Section 4.1.2). Approval will be issued by the Director of the Regulatory Unit after a specified review and discussion period. This period may be extended if the information submitted by the Contractor is insufficient in scope or depth to facilitate the reviews or if open issue resolution is not effectively supported by the Contractor.

3.3.2 Initial Safety Evaluation

The purpose of the Initial Safety Evaluation regulatory action is to assess the capability of the Contractor's waste processing approach to achieve subsequent authorizations for construction, operation, and deactivation. The results of this evaluation will be available to DOE, the customer, as input in choosing the Contractors to authorize to perform the Part B work. This evaluation will also provide a perspective on the regulatory risks associated with the Contractor’s firm-fixed-price proposal. Performed near the end of Part A, the Initial Safety Evaluation will address:

1) The degree to which the Contractor's proposed safety-related activities are being performed or can be performed in compliance with the approved SRD;

2) The degree to which the Contractor's proposed safety-related activities are being performed or can be performed in compliance with the approved ISMP;

3) The adequacy with which the hazards, including process hazards, attendant to the Contractor's proposed activities have been assessed and controlled;

4) The adequacy of the selection and definition of design basis events for the proposed facilities;

5) The acceptability of the results of analysis of representative design basis events;

6) The adequacy of the categorization of systems, structures, and components that are important to safety;

7) Adequacy of the projected safety basis for the facility and its operation;

8) The adequacy of the outlines of various plans, programs, and requests that will be generated and implemented in Part B;

9) The confidence associated with safety-related aspects of constructability, operability, reliability, availability, maintainability, and inspectability;

10) The resolvability of open issues, and

11) The adequacy of the draft deactivation plan.

The initial safety evaluation will be based on the Initial Safety Assessment (ISA) submitted by the Contractor, which includes an Initial Safety Analysis Report (ISAR) and the supplemental information described in Section 4.2.2. The format and content for this Contractor submittal will have been determined as part of the process for producing the SRD and will have been approved in the Standards Approval regulatory action described in Section 3.3.1.

An Initial Safety Evaluation Report (ISER) will be issued by the Director of the Regulatory Unit after a specified review and discussion period. Insufficient information either in scope or depth to facilitate the initial safety evaluation may result in open issues that will be noted in the ISER.

3.3.3 Authorization for Construction

The purpose of the Authorization for Construction regulatory action is to authorize the Contractor to begin construction of its facility for processing high-level radioactive waste. A construction authorization will be issued upon determination by the Director of the Regulatory Unit that:

1) The Contractor's safety-related activities are being conducted in accordance with its approved ISMP;

2) That proposed changes to the SRD and ISMP are acceptable;

3) The Contractor's design complies with the design-related part of the updated SRD;

4) The Contractor's design properly accounts for the natural and man-made external events associated with the designated site;

5) The Contractor is qualified by reason of experience and training to perform the proposed construction;

6) The Contractor is financially qualified to engage in the construction of the facility in accordance with the authorization agreement associated with the construction authorization;

7) The Contractor's construction procedures are adequate to ensure that the construction-

related part of the SRD will be properly implemented;

8) The Contractor's quality assurance plan is adequate and has been implemented such that the intended quality will be assured in the safety-related portions of the design, construction, and pre-operational testing and that the quality assurance records will attest thereto;

9) The radiological, nuclear, and process hazards associated with facility operation, including those from postulated accidents, have been adequately assessed, sufficiently controlled/mitigated, and adequately documented in a formally controlled Preliminary Safety Analysis Report (PSAR) to establish a basis for safe operation and an unambiguous definition of the safe-operating envelope;

10) The deactivation plan is acceptable;

11) The drafts of plans and programs to be finalized as elements of the operating authorization request and implemented during operation are adequate and acceptable; and

12) The Contractor has made a commitment to comply with the conditions of the authorization agreement associated with the construction authorization.

The Director of the Regulatory Unit will make this determination based on the Construction Authorization Request, which includes a Preliminary Safety Analysis Report (PSAR) and the supplemental information described in Section 4.3.2, submitted by the Contractor under oath and affirmation. The format and content for this Contractor submittal will have been determined as part of the process for producing the SRD and will have been approved in the Standards Approval regulatory action described in Section 3.3.1.

The construction authorization, which will be in the form of a construction authorization agreement, will be issued by the Director of the Regulatory Unit after a specified review and discussion period, culminating in the issuance of a Preliminary Safety Evaluation Report (PSER). This review and discussion period may be extended if the information submitted by the Contractor is insufficient in scope or depth to facilitate the above defined determinations or if open issue resolution is not effectively supported by the Contractor.

3.3.4 Authorization for Production Operations

The purpose of the Authorization for Production Operations regulatory action is to authorize the Contractor to begin introducing significant quantities of high-level radioactive waste into its facility. The authorization will be issued upon determination by the Director of the Regulatory Unit that:

1) The Contractor's safety-related activities are being conducted in accordance with its approved ISMP;

2) That proposed changes to the SRD and ISMP are acceptable;

3) The Contractor's as-built facility complies with the design-related, construction-related, and testing-related parts of the final SRD;

4) The Contractor's as-built facility properly accounts for the natural and man-made external events associated with the designated site;

5) The Contractor is qualified by reason of experience and training to conduct the proposed operation;

6) The Contractor is financially qualified to engage in the operation of the facility in

accordance with the authorization agreement associated with the operating authorization;

7) The Contractor's operating procedures are adequate to ensure safe operation of the facility and ensure that all operations are conducted within the approved operating authorization basis;

8) The Contractor's quality assurance plan is adequate and has been implemented such that the intended quality has been achieved in the safety-related portions of the design, construction, and pre-operational testing, and the quality assurance records attest thereto;

9) The Contractor's physical protection provisions are adequate to prevent unauthorized access to structures, systems, and components important to safety;

10) The Contractor's personnel training and certification are adequate for the safe operation of the plant;

11) The Contractor's deactivation plan remains adequate to protect the health and safety of the public and the workers, and adequate financial arrangements have been made to ensure its implementation;

12) The radiological, nuclear, and process hazards associated with as-built facility operation, including those from postulated accidents, have been adequately assessed, sufficiently controlled/mitigated, and adequately documented in a formally controlled Final Safety Analysis Report (FSAR) to ensure safe operation and an unambiguous definition of the safe-operating envelope;

13) Adequate Technical Safety Requirements (TSRs) have been established to ensure that operations are conducted well within the safe-operating envelope;

14) The startup test program has been successfully completed and confirms the intended safety characteristics of the facility;

15) An adequate emergency plan is in place and operational;

16) All other plans and programs required to be finalized and implemented in support of production operations are acceptable;

17) The Contractor has made a commitment to comply with the conditions of the authorization agreement associated with the operating authorization;

18) The Contractor has made a commitment to comply with the provisions of the regulatory oversight program defined in Section 3.3.4 and Section 4.4 of this document;

19) The Contractor's conduct of operations program for the operations phase is adequate, and it is fully implemented; and

20) A formal operational readiness review has been successfully completed and documented.

The Director of the Regulatory Unit will make this determination based on the Operating Authorization Request, which includes a Final Safety Analysis Report (FSAR) and supplemental information described in Section 4.4.2 submitted by the Contractor under oath and affirmation. The format and content for this Contractor submittal will have been determined as part of the process for producing the SRD and will have been approved in the Standards Approval regulatory action described in Section 3.3.1.

The operating authorization, which will be in the form of a operating authorization agreement, will be issued by the Director of the Regulatory Unit after a specified review and discussion period, culminating in the issuance of a Final Safety Evaluation Report (FSER). This

review and discussion period may be extended if the information submitted by the Contractor is insufficient in scope or depth to facilitate the above defined determinations or if open issue resolution is not effectively supported by the Contractor.

3.3.5 Oversight Process Determination

The purpose of this regulatory action is to monitor the operation of the Contractor's facility to ensure that the authorization basis and the conditions in the authorization agreement are not violated. The regulatory oversight program will consist of the following elements:

1) Annual review and assessment of physical, process, and operational changes;

2) Annual review and assessment of site-related changes;

3) Annual review and assessment of changes to equipment and structures, particularly those that are important to safety;

4) Annual review and assessment of changes in the codes, standards, and regulations that form the authorization basis and the conditions in the authorization agreement;

5) Annual review of the Contractor's analysis of the effects of the changes noted in items 1 - 4 above, including any analyses and determinations associated with potential unreviewed safety questions;

6) Review and assessment of event reports;

7) Review and assessment of the effectiveness of emergency response actions and drills;

8) Review and assessment of the effectiveness of the Contractor's assessments of its conduct of operations;

9) On-site inspections of records, premises, and activities, particularly those associated with conduct of operations;

10) Consideration of amendments to the authorization to operate or to the authorization agreement, including review and approval of changes to the FSAR;

11) Review and approval of proposed changes to the SRD and ISMP;

12) Review and approval of proposed changes to the TSRs;

13) Consideration of corrective actions, including suspension of operations; and

14) Communication of noncompliances to the DOE Enforcement and Inspection staff for enforcement consideration under 10 CFR 820.

This oversight function will be performed based on information submitted by the Contractor under oath and affirmation, on direct inspections, and on other reliable, documented information. The format and content for the information to be submitted by the Contractor will have been determined as part of the process for producing the SRD and will have been approved in the Standards Approval regulatory action described in Section 3.3.1.

Amendments to the operating authorization or to the operating authorization agreement will be issued after an agreed upon review and discussion period. This review and discussion period may be extended if the information submitted by the Contractor is insufficient in scope or depth to facilitate the review and approval of the amendments or if open issue resolution is not effectively supported by the Contractor.

3.3.6 Authorization for Deactivation

The purpose of the Authorization for Deactivation regulatory action is to authorize deactivation of the Contractor's facility following a stipulation by the Contractor to cessation of the waste processing activities at the facility. The authorization will be issued upon determination by the Director of the Regulatory Unit that:

1) The Contractor has submitted a final plan for deactivation;

2) The plan adequately addresses the current conditions at the facility and associated site;

3) The selected approach for deactivation is adequate given the facility and site conditions;

4) The controls and limits on procedures and equipment to protect worker and public health and safety are adequate;

5) The proposed final radiation surveys are adequate;

6) The commitment of funds is sufficient to complete the deactivation activities, to perform final radiation surveys, and to properly dispose of the wastes generated; and

7) The schedule for performing the deactivation activities is consistent with assuring no undue radiological, nuclear, and hazardous chemical risks to the public, Hanford Site workers, or the workers.

The Director of the Regulatory Unit will make this determination based on the Deactivation Authorization Request, which includes a Deactivation Safety Assessment and supplemental information described in Section 4.6, submitted by the Contractor under oath and affirmation. The format and content for this Contractor submittal will have been determined as part of the process for producing the SRD and will have been approved in the Standards Approval regulatory action described in Section 3.3.1.

The deactivation authorization, which will be in the form of a deactivation authorization agreement, will be issued by the Director of the Regulatory Unit after a specified review and discussion period, culminating in the issuance of a Deactivation Safety Evaluation Report. This review and discussion period may be extended if the information submitted by the Contractor is insufficient in scope or depth to facilitate the above defined determinations or if open issue resolution is not effectively supported by the Contractor.

4.0 Detailed Regulatory Implementation

Figure 2 shows the overall time-line for accomplishing the regulatory actions described in Section 3.0. This is not intended as a detailed schedule for the regulatory actions. Rather, it provides the general time frames in which these action must occur. The Contractor shall define the detailed schedule for submittal of its documentation to support these actions as part of its ISMP, taking into account the review and approvals reference schedules in Section 4.0.

This time-line is based on the procurement strategy in which up to three contracts will initially be awarded. The three Contractors will develop their designs to a maturity level commensurate with allowing firm-fixed-price proposals to be prepared for performing the remainder of the design, as well as, the construction, operation, and deactivation and commensurate with initiating permitting actions. Two of the three Contractors will be selected to perform the Part B work.

4.1 Standards Approval

4.1.1 Review Process

The reference review and approval schedule for the Standards Approval regulatory action is shown in Figure 3. As shown in Figure 2, it is expected that the Contractor's submittal package for this action will be delivered to the Regulatory Unit about midway through Part A. If the submittal package is sufficient to proceed with the review process and if the Contractor supports the process with written responses to prepared questions and a discussion meeting, according to the reference schedule, the SRD and ISMP approvals will be issued by the Director of the Regulatory Unit in a total elapsed time of 14 weeks. If the package is rejected, the review process will be rescheduled. The insufficiency of the information will be explained in a letter of rejection transmitted to the Contractor within one week after the rejection decision has been reached.

4.1.2 Contractor Input

The Contractor shall provide written notice of the intent to submit the Standards Approval submittal package 30 days prior to delivery. The Standards Approval submittal package shall consist of the following documentation:

1) The Contractor's recommended set of radiological, nuclear, and process standards for design, construction, operation, deactivation, and regulatory submittals in the form of a SRD;

2) The Contractor's certification that the set of radiological, nuclear, and process standards in the SRD will, when implemented, will provide adequate safety, comply with all applicable laws and regulations, and conform to the DOE-stipulated top-level safety standards and principles;

3) The hazards assessment used to facilitate the selection of the standards;

4) The hazards control strategy implemented in the design and proposed operations;

5) Description of the process and facility design and its proposed operation;

6) The Contractor's treatment of the top-level radiological, nuclear, and process safety standards and principles;

7) The rationale for the selection of the standards and the adequacy of the set;

8) The standards identification process used and the credentials of the participants;

9) The standards confirmation process used and the credentials of the participants;

10) The Contractor's approval process used for the set of standards and the basis for the approval;

11) The Contractor's ISMP, which shall

    a) Define the key safety-related activities to be performed by the Contractor;

    b) Specify the standards-based management processes to be used by the Contractor to ensure that radiological, nuclear, and process safety is adequately defined (i.e., tailored to the nature and level of hazards, including process hazards), implemented, and maintained;

    c) Ensure that the Contractor is in compliance with DOE Nuclear Safety Regulations, in conformance with the DOE-stipulated top-level safety standards and principles, and in compliance with the SRD;

    d) Define the Contractor's interfaces with other regulatory regimes such as environmental protection, occupational safety, and safeguards and security, and define the processes for resolving conflicting requirements at these interfaces and for ensuring safety adequacy at these interfaces (i.e., ensuring that safety "gaps" do not occur);

    e) Specify the expected flow and schedule of the Contractor's safety-related work and deliverables, including interactions with the Regulatory Unit;

    f) Describe the self-assessment functions to be employed by the Contractor;

    g) Describe the Contractor's approach for tailoring its radiological, nuclear, and process safety deliverables and actions commensurate with the nature and level of hazards associated with its waste processing activities; and

    h) Identify roles, responsibilities, and authorities for defining, implementing, and maintaining safety.

12) ISMP compliance with applicable laws and regulations, particularly the implementation plans required in the 10 CFR 830 rules;

13) ISMP conformance to the top-level radiological, nuclear, and process standards and principles contained in DOE/RL-96-0006.

The Contractor shall also prepare written responses to review questions and shall participate a discussion meeting with the Regulatory Unit hosted by the Contractor. The Contractor shall also submit any other information that could materially affect the determination by the Director of the Regulatory Unit to approve the SRD and the ISMP.

4.1.3 Regulatory Unit Actions

The Regulatory Unit will conduct the review in the following manner:

1) Assign a review manager from the Regulatory Unit to direct the reviews of the SRD and ISMP;

2) Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence;

3) Review the Standards Review submittal package for completeness and adequacy within one week from the day of its receipt. Upon completing the review, issue a notice to the

Contractor in writing of the acceptability of the package. If the package is rejected, list the reasons for the rejection and the necessary corrective actions. After the package is accepted for review, the Regulatory Unit may request additional information from the Contractor to clarify or supplement material in the package;

4) Perform the reviews in accordance with review plans previously developed by the Regulatory Unit;

5) Further clarify previously provided Contractor information and responses to additional information requests at a Contractor/Regulatory Unit meeting. Any resulting agreements, understandings, and new information shall be documented and submitted by the Contractor as additional information submitted for review;

6) Prepare a draft SRD Evaluation Report and a draft approval letter (may be conditional);

7) Prepare a draft ISMP Evaluation Report and a draft approval letter (may be conditional);

8) Distribute the draft SRD Evaluation Report, the draft ISMP Evaluation Report, and the draft approval letters for public and Contractor comment; and

9) Issue the final SRD Evaluation Report, the final ISMP Evaluation Report, final approval letters, and responses to public comment.

4.2 Initial Safety Evaluation

4.2.1 Review Process

The reference schedule for the Initial Safety Evaluation regulatory action is shown in Figure 4. As shown in Figure 2, it is expected that the Contractor's submittal package for this action, the Initial Safety Assessment (ISA), will be delivered to the Regulatory Unit late in Part A. If the submittal package is sufficient to proceed with the standards review process and if the Contractor supports the process with written responses to prepared questions and a discussion meeting, according to the reference schedule, the Initial Safety Evaluation Report will be issued by the Director of the Regulatory Unit in 9 weeks. If the package is rejected, the review process will be rescheduled. The insufficiency of the information will be explained in a letter of rejection transmitted to the Contractor within one week after the rejection decision has been reached. Rescheduling the review may not permit a full review of the ISA because of the constraints of the overall procurement schedule. If so, the partial review and associated results will be summarized in the ISER along with all open issues.

4.2.2 Contractor Input

The Contractor shall provide written notice of the intent to submit the Initial Safety Assessment submittal package 30 days prior to delivery. This submittal package shall consist of the following documentation:

1) Description of the design developed during Part A and the proposed facility operations;

2) Description of the Contractor's site and its location within the Hanford Site;

3) An assessment of compliance to the approved SRD and the ISMP;

4) Description of hazards, including process hazards, and hazards controls implemented in the design and operations;

5) Description of potential design-basis events;

6) Analysis of the potential design-basis events;

7) Preliminary safety acceptance criteria against which the consequences of the potential design-basis events are compared for acceptability;

8) Description of structures, systems, and components designated as important to safety and the rationale for their selection;

9) The Contractor's evaluations of constructability, operability, reliability, availability, maintainability, and inspectability;

10) An Initial Safety Analysis Report that

   a) Defines the projected safety basis for the facility (safety envelope) in terms of physical design, structures with prescribed safety functions, systems with prescribed safety functions, equipment with prescribed safety functions, operating modes, operating conditions, representative off-normal internal events, representative external events, representative safety analyses and results, major uncertainties in data and analyses;

   b) Describes how the facility should perform such that the radiological, nuclear, and process safety standards and requirements in the SRD and in applicable regulations are met; and

   c) Describes how adequate protection of the public, the workers, and the environment should be achieved;

11) Draft deactivation plan;

12) Outlines of the

   a) Construction Authorization Request;
   b) Operating Authorization Request;
   c) Emergency Response Plan;
   d) Unreviewed Safety Question Plan;
   e) Conduct of Operations Plan;
   f) Technical Safety Requirements;
   g) Training and Qualification Plan;
   h) Maintenance Implementation Plan;
   i) Occurrence Reporting Procedures;
   j) Environmental Radiological Protection Program;
   k) Radiation Protection Program;
   l) Operational Analysis and Assessment Reports;
   m) Deactivation Safety Assessment; and
   n) Deactivation Authorization Request;

The Contractor shall also prepare written responses to review questions and shall participate in a discussion meeting with the Regulatory Unit hosted by the Contractor. The Contractor shall also submit any other information that could materially affect this evaluation by the Director of the Regulatory Unit.

4.2.3 Regulatory Unit Actions

The Regulatory Unit will conduct the review in the following manner:

1) Assign a review manager from the Regulatory Unit to direct the initial safety evaluation;

2) Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence;

3) Review the submittal package for completeness and adequacy within one week from the day of its receipt. Upon completing the review, issue a notice to the Contractor in writing of the acceptability of the package. If the package is rejected, list the reasons for the rejection and the necessary corrective actions. After the package is accepted for review, the Regulatory Unit may request additional information from the Contractor to clarify or supplement material in the package.

4) Perform the review in accordance with a review plan previously developed by the Regulatory Unit;

5) Further clarify previously provided Contractor information and responses to additional information requests at a Contractor/Regulatory Unit meeting. Any resulting agreements, understandings, and new information shall be documented and submitted by the Contractor as additional information submitted for review;

6) Prepare and issue a final Initial Safety Evaluation Report;

4.3 Authorization for Construction

4.3.1 Review Process

The reference review and approval schedule for the Authorization for Construction regulatory action is shown in Figure 5. As shown in Figure 2, it is expected that the Contractor's submittal package for this action, the Construction Authorization Request, will be delivered to the Regulatory unit in Part B before substantial construction involving safety-related features has been initiated. If the submittal package is sufficient to proceed with the review process and if the Contractor supports the process with written responses to prepared questions and with scheduled discussion meetings, according to the reference schedule, the construction authorization will be issued by the Director of the Regulatory Unit in a total elapsed time of 25 weeks. If the package is rejected, the review process will be rescheduled. The insufficiency of the information will be explained in a letter of rejection transmitted to the Contractor within one week after the rejection decision has been reached.

4.3.2 Contractor Input

The Contractor shall provide written notice of the intent to submit the Construction Authorization Request submittal package 60 days prior to delivery. This submittal package shall consist of the following documentation:

1) Description of the Contractor's site and its location within the Hanford Site;

2) Description of natural-phenomena and man-made external hazards at the Contractor's site, the selected design-basis external events, and the rational for their selection;

3) Description of high-level radioactive waste handling and treatment processes;

4) Description of planned facility operations;

5) Description of facility structures, systems, and components including those designated as important to safety;

6) The current SRD and the ISMP and an assessment of compliance to the SRD and the ISMP (note the changes relative to the SRD and ISMP approved by the regulation action of Section 4.1);

7) Detailed design data and design drawings;

8) Analysis of radiological, nuclear, and process hazards for the final design;

9) Description of facility features and functions provided to control the radiological, nuclear, and process hazards;

10) Description of the range of off-normal events and postulated accidents that could initiate internal to the Contractor's facility, the selected design-basis internal events, and the rationale for their selection;

11) Analysis of hazards-control features during all expected facility operating modes, off-normal conditions, and design basis internal and external events;

12) Potential safety limits and the justification for their selection;

13) Description of planned safety-related testing to be performed, including the purpose of each test, expected data, and a description of the test and associated equipment;

14) Description of quality assurance program, including implementation procedures, employed during the design, and to be employed during construction, safety-related testing, and pre-operational testing;

15) A PSAR that

    a) Defines the analyzed safety basis for the facility (safety envelope) in terms of physical design, structures with prescribed safety functions, systems with prescribed safety functions, equipment with prescribed safety functions, operating modes, operating conditions, off-normal internal events considered, external events considered, assumptions made, uncertainties in data and analyses, safety limits, and operating limits;

    b) Demonstrates that the facility should perform such that the radiological, nuclear, and process safety requirements in the SRD and in applicable regulations should be met; and

    c) Demonstrates that adequate protection of the public, the workers, and the environment should be achieved;

16) The Contractor's technical and experience qualifications to construct the plant;

17) The Contractor's financial capability to construct the plant;

18) Description of the D&D features provided in the design and the final deactivation plan;

19) The procedures to be used to implement the construction and pre-operational testing portions of the SRD and the ISMP;

20) Drafts of the

    a) Emergency Response Plan;
    b) Unreviewed Safety Question Plan;
    c) Conduct of Operations Plan;
    d) Technical Safety Requirements;
    e) Training and Qualification Plan;
    f) Maintenance Implementation Plan;
    g) Occurrence Reporting Procedures;
    h) Environmental Radiological Protection Program; and
    i) Radiation Protection Program;

The Contractor shall also prepare written responses to review questions and shall participate in up to two discussion meetings with the Regulatory Unit hosted by the Contractor. The Contractor shall also submit any other information that could materially affect the determination by the Director of the Regulatory Unit to grant a construction authorization.

Note: During the construction activities, the Contractor shall support regulatory oversight aimed at assuring that the construction authorization agreement is not violated or that formal amendment processes are facilitated.

4.3.3 Regulatory Unit Actions

The Regulatory Unit will conduct the review in the following manner:

1) Assign a review manager from the Regulatory Unit to direct the Construction Authorization Request review;

2) Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence;

3) Review the submittal package for completeness and adequacy within two weeks from the day of its receipt. Upon completing the review, issue a notice to the Contractor in writing of the acceptability of the package. If the package is rejected, list the reasons for the rejection and the necessary corrective actions. After the package is accepted for review, the Regulatory Unit may request additional information from the Contractor to clarify or supplement material in the package;

4) Perform the review in accordance with a review plan previously developed by the Regulatory Unit;

5) Further clarify previously provided Contractor information and responses to additional information requests during two Contractor/Regulatory Unit meetings. Any resulting agreements, understandings, and new information shall be documented and submitted by the Contractor as additional information submitted for review;

6) Prepare a draft Preliminary Safety Evaluation Report (PSER) and draft construction authorization agreement ;

7) Distribute the draft PSER and the draft construction authorization agreement for public and Contractor comment;

8) Issue the final PSER, the final construction authorization agreement, and responses to public comment.

Note: During the construction activities, the Regulatory Unit will perform regulatory oversight aimed at assuring that the construction authorization agreement is not violated and that formal amendment processes are executed.

4.4 Authorization for Production Operations

4.4.1 Review Process

The reference review and approval schedule for the Authorization for Production Operations regulatory action is shown in Figure 6. As shown in Figure 2, it is expected that the Contractor's submittal package for this action, the Operating Authorization Request, will be delivered to the Regulatory unit in Part B near the end of the construction/pre-operational testing period. If the submittal package is sufficient to proceed with the review process for an operating authorization and if the Contractor supports the process with written responses to prepared questions and with scheduled

discussion meetings, according to the reference schedule, the authorization will be issued by the Director of the Regulatory Unit in a total elapsed time of 28 weeks. If the package is rejected, the review process will be rescheduled. The insufficiency of the information will be explained in a letter of rejection transmitted to the Contractor within one week after the rejection decision has been reached.

4.4.2 Contractor Input

The Contractor shall provide written notice of the intent to submit the Operating Authorization Request submittal package 60 days prior to delivery. This submittal package shall consist of the following documentation:

1) Final description of the Contractor's site and its location within the Hanford Site (emphasize changes from the construction authorization basis);

2) Final description of the natural-phenomena and man-made external hazards at the Contractor's site, selected design-basis external events, and rationale for their selection (emphasize changes from the construction authorization basis);

3) Final description of the high-level radioactive waste handling and treatment processes (emphasize changes from the construction authorization basis);

4) Final description of the facility operations (emphasize changes from the construction authorization basis);

5) Final description of the facility structures, systems, and components including those designated as important to safety (emphasize changes from the construction authorization basis);

6) The final SRD and ISMP, and an assessment of compliance to the SRD and the ISMP (emphasize changes from the construction authorization basis);

7) Final design data and design drawings that clearly indicate the safety features of the plant and their characteristics (emphasize changes from the construction authorization basis);

8) Final analysis of radiological, nuclear, and process hazards as controlled by the engineered safety features (emphasize changes from the construction authorization basis);

9) An FSAR that

   a) Fully defines the analyzed safety basis for the facility (safety envelope) in terms of physical design, structures with prescribed safety functions, systems with prescribed safety functions, equipment with prescribed safety functions, operating modes, operating conditions, off-normal internal events considered, external events considered, assumptions made, uncertainties in data and analyses, safety limits, and operating limits;

   b) Demonstrates that the facility will perform such that the radiological, nuclear, and process safety requirements in the SRD and in applicable regulations will be met; and

   c) Demonstrates that adequate protection of the public, the workers, and the environment will be achieved;

10) The Contractor's technical and experience qualifications to operate the facility;

11) The Contractor's financial capability to operate the facility;

12) Final description of the D&D features provided in the design and any changes in the deactivation plan, including financial arrangements that have been made to ensure its implementation (emphasize changes from the construction authorization basis);

13) Procedures to be used to implement the operations portions of the SRD and ISMP;

14) Final Technical Safety Requirements and the rationale for their selection;

15) Final Training and Qualification Plan;

16) Certification that operations personnel are ready and able to perform their intended functions;

17) Description of the safety-related testing program, including pre-operational facility and equipment tests, and the results of the tests versus the test requirements and acceptance criteria;

18) Final description of the quality assurance program, including implementation procedures employed during the design, construction, safety-related testing, and pre-operational testing and documentation of the effectiveness of the QA program implementation in assuring that the facility is construction as intended;

19) Final description of the expected radiological effluents from the facility and the associated monitoring and reporting programs;

20) Final description of the expected radioactive wastes (non-product wastes) from facility operations and the associated storage, handling, and disposal programs;

21) Final Conduct of Operations Plan to be implemented during the facility operations phase and evidence that the plan is fully implemented;

22) Final operating procedures, including those for recovery from off-normal events;

23) Final submissions of the

    a) Unreviewed Safety Question Plan;
    b) Maintenance Implementation Plan;
    c) Occurrence Reporting Procedures;
    d) Environmental Radiological Protection Program;
    e) Radiation Protection Program;
    f) Emergency Response Plan and procedures;

24) Evidence that the intended emergency response capability is qualified and functional;

25) Final description of the physical protection program and associated physical and administrative features;

26) The Contractor's understanding of and commitment to comply with the provisions of the regulatory oversight program during the operations phase; and

The Contractor shall also support a formal operational readiness review, prepare written responses to review questions, and participate in up to three discussion meetings with the Regulatory Unit hosted by the Contractor. The Contractor shall also submit any other information that could materially affect the determination by the Director of the Regulatory Unit to grant an operating authorization.

4.4.3 Regulatory Unit Actions

The Regulatory Unit will conduct the review in the following manner:

1) Assign a review manager from the Regulatory Unit to direct the Operating Authorization Request review;

2) Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence;

3) Review the submittal package for completeness and adequacy within three weeks from the day of its receipt. Upon completing the review, issue a notice to the Contractor in writing of the acceptability of the package. If the package is rejected, list the reasons for the rejection and the necessary corrective actions. After the package is accepted for review, the Regulatory Unit may request additional information from the Contractor to clarify or supplement material in the package.

4) Perform the review in accordance with a review plan previously developed by the Regulatory Unit;

5) Further clarify previously provided Contractor information and responses to additional information requests during three Contractor/Regulatory Unit meetings. Any resulting agreements, understandings, and new information shall be documented and submitted by the Contractor as additional information submitted for review;

6) Perform a formal operational readiness review;

7) Prepare a draft Final Safety Evaluation Report (FSER) and draft operating authorization agreement;

8) Distribute the draft FSER and the draft operating authorization agreement for public and Contractor comment; and

9) Issue the final FSER, the final operating authorization agreement, and responses to public comment.

4.5 Oversight Process Determination

4.5.1 Oversight Process

The oversight process for determining that the operating authorization basis and the operating authorization agreement are not violated during the production operations phase of the Contractor's facility will consist of the following elements:

1) Periodic reviews of annual Contractor reports and self-assessments;

2) Unscheduled evaluations of unusual occurrences;

3) Unscheduled intermittent reviews of authorization amendments and Unreviewed Safety Questions (USQs);

4) Continuous in-facility inspections; and

5) Corrective actions.

The oversight process begins with the start of operation following the issuance of the operating authorization and ends at the point in time that the operating authorization is terminated.

As shown in Figure 2, it is expected that the oversight process will be active during the latter part of Part B.

The focus of the oversight process will be on

1) In-facility verification of the completeness and correctness of the information provided by the Contractor to the Regulatory Unit;

2) Ensuring that changes to the facility structures, systems, equipment, processes, procedures, etc. are properly assessed and, if necessary, addressed promptly with the Director of the Regulatory Unit;

3) Potential challenges to the operating authorization agreement; and

4) The nature and frequency of off-normal conditions and occurrences.

4.5.2 Contractor Input

The Contractor shall:

1) Submit documentation describing any proposed physical changes to the facility, procedural changes to operations, or administrative changes associated with operation that could impact the operating authorization basis or compliance with the operating authorization agreement, and documentation of any analyses or assessments performed to determine the impacts of these proposed changes prior to implementing the changes;

2) Annually submit documentation cataloging significant physical, procedural, and administrative changes over a given year and provide assessments of the impacts of the changes;

3) Annually submit documentation cataloging significant changes in relevant codes, standards, and regulations and provide assessment of the impacts of implementing these changes;

4) Submit documentation of the Contractor's self-assessments of its conduct of operations, of various drills including emergency response exercises, of operator performance, etc.;

5) Submit unusual occurrence reports describing the event or condition, the Contractor's assessment of implications and causes, and the Contractor's recommended corrective actions;

6) Support in-facility regulatory inspections of operations; tests; maintenance activities; records; facility, system, and equipment status; operating and administrative procedures; unusual occurrences; and log-books;

7) Provide written notice of intent to submit a request to amend the operating authorization 30 days prior to the request;

8) Submit all necessary information to support the review and evaluation of any such requested amendments;

9) Support requests for additional information and discussions during the reviews associated with requested amendments;

10) Maintain the FSAR, SRD, ISMP, TSR, and key supporting documents that are materially part of the operating authorization basis in a current state (annual updates unless circumstances warrant otherwise);

11) Support the resolution of USQs;

12) Perform back-fit assessments as requested; and

13) Support annual safety performance meetings in which the facility safety record is presented, safety performance is discussed, and safety plans are described.

4.5.3 Regulatory Unit Actions

The Regulatory Unit will perform the oversight in the following manner:

1) Assign an oversight manager from the Regulatory Unit to direct the oversight process;

2) Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence;

3) Review proposed amendments to the operating authorization agreement;

4) Issue amendments to the operating authorization agreement;

5) Review and disposition USQs;

6) Review all change reports, self-assessment reports, unusual occurrence reports, submitted by the Contractor and in-facility inspection reports to determine needs for modifications to the authorization basis and associated controlled documents or amendments to the operating authorization agreement;

7) Issue back-fit requirements, as necessary, based on reviews of Contractor's back-fit assessments;

8) Perform in-facility inspections;

9) Formulate and issue corrective actions; and

10) Communicate regulatory noncompliances to the DOE Enforcement and Investigation staff.

4.6 Authorization for to Deactivation

4.6.1 Review Process

The reference review and approval schedule for the Authorization for Deactivation regulatory action is shown in Figure 7. As shown in Figure 2, it is expected that the Contractor's submittal package for this action, the Deactivation Authorization Request, will be delivered to the Regulatory unit near the end of the production operations period of Part B. If the submittal package is sufficient to proceed with the review process for deactivation authorization and if the Contractor supports the process with written responses to prepared questions and with scheduled discussion meetings, according to the reference schedule, the deactivation authorization will be issued by the Director of the Regulatory Unit in a total elapsed time of 23 weeks. If the package is rejected, the review process will be rescheduled. The insufficiency of the information will be explained in a letter of rejection transmitted to the Contractor within one week after the rejection decision has been reached.

4.6.2 Contractor Input

The Contractor shall provide written notice of the intent to submit the Deactivation Authorization Request submittal package 60 days prior to delivery. This submittal package shall consist of the following documentation:

1) A final deactivation plan;

2) Description of the post-operations conditions of the facility and the associated site;

3) Rationale for the selection of the deactivation approach;

4) The hazards assessment for the selected deactivation approach and the results;

5) Description of the controls and limits that will be imposed through procedures and on equipment to protect worker and public health and safety;

6) Description of the final radiation survey to be performed;

7) The funding commitments and arrangements for the deactivation activities, including final radiation survey and disposal of wastes; and

8) The proposed schedule for the deactivation and providing an assessment of the risks associated with any delays in performing the deactivation;

The Contractor shall also prepare written responses to review questions and shall participate a discussion meeting with the Regulatory Unit hosted by the Contractor. The Contractor shall also submit any other information that could materially affect the determination by the Director of the Regulatory Unit to grant a deactivation authorization.

Note: During the deactivation activities, the Contractor shall support regulatory oversight aimed at assuring that the deactivation authorization agreement is not violated or that formal amendment processes are facilitated.

4.6.3 Regulatory Unit Actions

The Regulatory Unit will conduct the review in the following manner:

1) Assign a review manager from the Regulatory Unit to direct the Deactivation Authorization Request review;

2) Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence;

3) Review the submittal package for completeness and adequacy within one week from the day of its receipt. Upon completing the review, issue a notice to the Contractor in writing of the acceptability of the package. If the package is rejected, list the reasons for the rejection and the necessary corrective actions. After the package is accepted for review, the Regulatory Unit may request additional information from the Contractor to clarify or supplement material in the package;

4) Perform the review in accordance with a review plan previously developed by the Regulatory Unit;

5) Further clarify previously provided Contractor information and responses to additional information requests during two Contractor/Regulatory Unit meetings. Any resulting agreements, understandings, and new information shall be documented and submitted by the Contractor as additional information submitted for review;

6) Prepare a draft Deactivation Safety Evaluation Report (DSER) and draft deactivation authorization agreement;

7) Distribute the draft DSER and the draft deactivation authorization agreement for public and Contractor comment; and

8) Issue the final DSER, the final deactivation authorization agreement, and responses to public comment.

Note: During the deactivation activities, the Regulatory Unit will perform regulatory oversight aimed at assuring that the deactivation authorization agreement is not violated and that formal amendments processes are executed.

4.7 Proprietary Information

The Director of the Regulatory Unit, including any associated technical support teams, and review and oversight bodies, will adopt and implement procedures and processes necessary to protect the Contractor's proprietary information. The procedures and processes will be reviewed and approved by the Contractor prior to any interactions between the Contractor and the Regulatory Unit involving the Contractor's proprietary information.

4.8 Back-fit

As used in this section, back-fit means the addition, elimination, or modification of: 1) structures, systems, or components of the facility; or 2) procedures or organizations required to operate the facility after the operating authorization has been issued. The Director of the Regulatory Unit will require a back-fit if the Regulatory Unit determines, and an independent review concurs, that such action is necessary to:

1) Ensure adequate protection of worker or public health and safety;

2) Bring the facility and its operation into compliance with the operating authorization and the conditions attached thereto;

3) Bring the facility and its operation into compliance with current Federal, State, and local regulations;

4) Bring the facility and its operation into compliance with any Compliance Orders issued under Subpart C of 10 CFR 820; or

5) Achieve a substantial increase in overall protection of worker or public health and safety, and the associated implementation costs are justified.

In support of the implementation of this back-fit policy, the Contractor shall provide assessments of proposed back-fits, including implementation approaches and associated safety, cost, and operational impacts, and shall submit alternative approaches, if any, to achieve the expressed purpose of a particular back-fit.

4.9 Authorization Revocation

The operating authorization may be revoked or suspended in whole or in part by the Director of the Regulatory Unit for any of the following:

1) A material false statement in the request for an authorization or associated material presented under oath and affirmation as the authorization basis;

2) A revelation of conditions or statements of fact that would have been a basis for refusal to grant an authorization had such conditions or facts been known by the Director of the Regulatory Unit at the time the authorization was granted;

3) Failure to operate the facility in accordance with the operating authorization agreement;

4) Failure to comply with applicable laws and regulations; or

5) Failure to comply with Compliance Orders issued under Subpart C of 10 CFR 820.

To ensure adequate protection to worker or public health and safety, a revocation of the operating authorization and associated cessation of operation (treatment of high-level waste) shall be a planned event. The Contractor shall ensure that the facility is placed and maintained in a safe state that is fully restartable using approved operating procedures.

4.10 Suspension of Operation

The Director of the Regulatory Unit may order the suspension of facility operation if a clear and present danger to the workers or the public is evidenced. Such an action will be taken only after specified procedures have been followed. To ensure adequate protection to worker or public health and safety, an ordered suspension of operation (treatment of high-level waste) shall be a planned event. The Contractor shall ensure that the facility is placed and maintained in a safe state that is fully restartable using approved operating procedures.

4.11 Issue Resolution

In general, issues will be addressed by the Regulatory Unit based on factual information and objective standards or expectations. However, factual information can have subjective aspects: its quality, its interpretation, its applicability, its sufficiency, etc., and use of standards is not without subjective elements. Therefore, disagreements between the Regulatory Unit and the Contractor may occur. To ensure that issues involving subjective elements are expeditiously resolved, a definitive resolution process will be developed and implemented by the Director of the Regulatory Unit after consultation with the Contractor. The elements of this process will include:

1) Development of a clear statement of the issue;

2) Delineation of the facts versus subjective elements;

3) Establishment of agreement on the root cause of the disagreement;

4) Development of an action plan to address (remove) the root cause;

5) Development of alternatives to avoid the root-cause;

6) Formulation of definitive alternatives for issue resolution with implications of each (cost, schedule, safety margins, etc.);

7) Independent review input; and

8) Ruling on the matter by the Director of the Regulatory Unit.

5.0 Figures

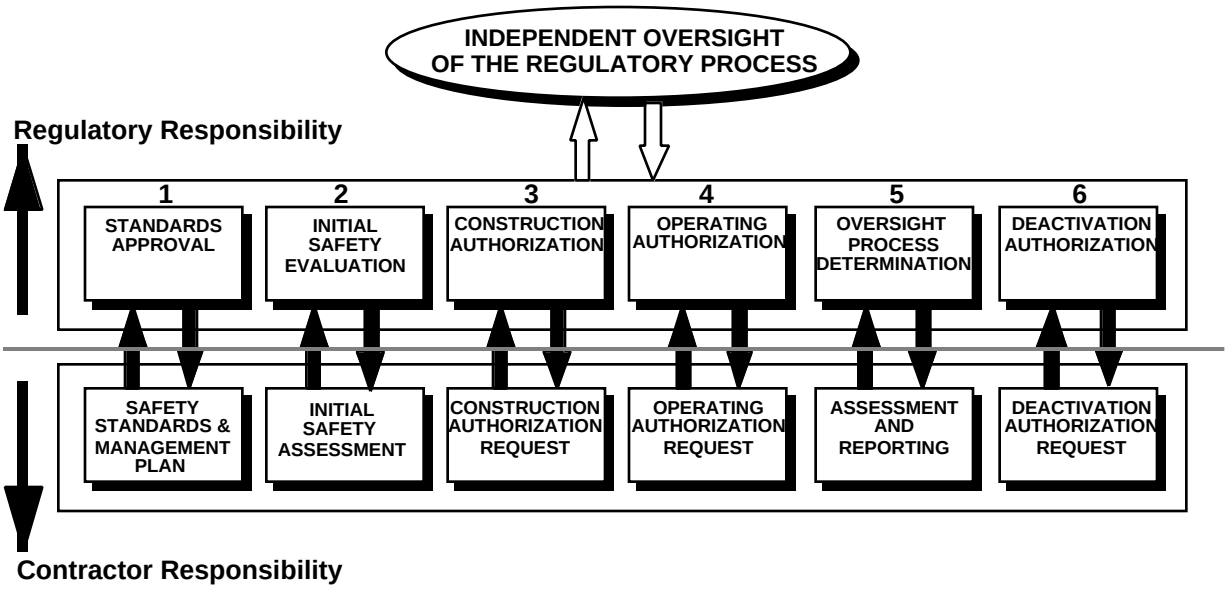

Figure 1. Comprehensive Regulatory Process.

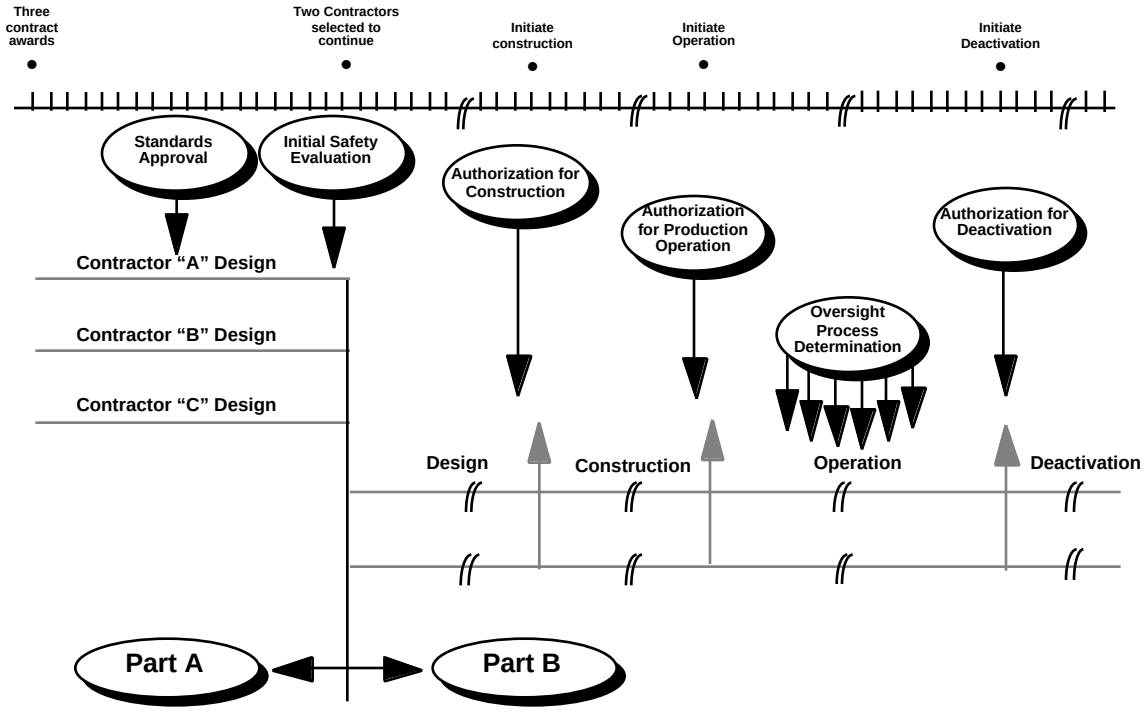

Figure 2. Overall Time Line for Regulatory Actions.

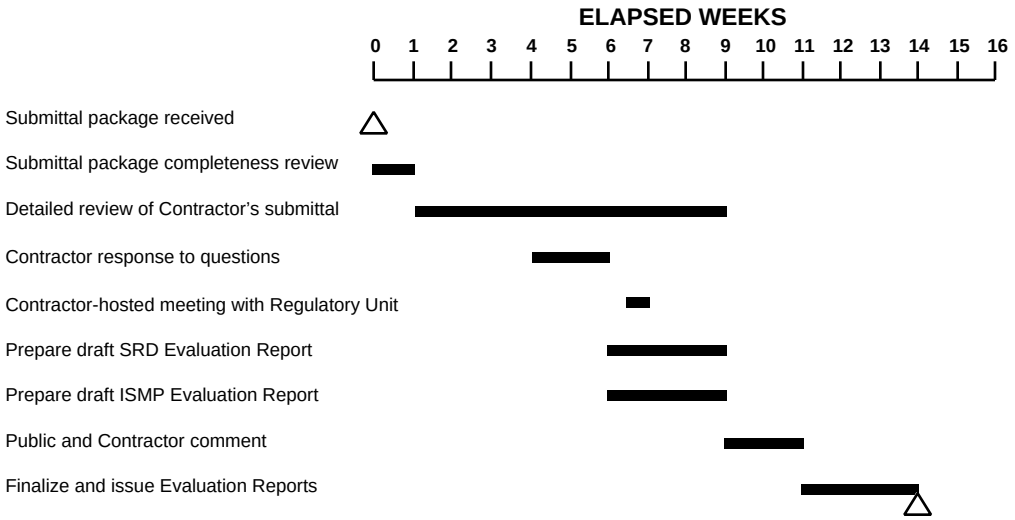

Figure 3. Reference Schedule for Standards Approval.

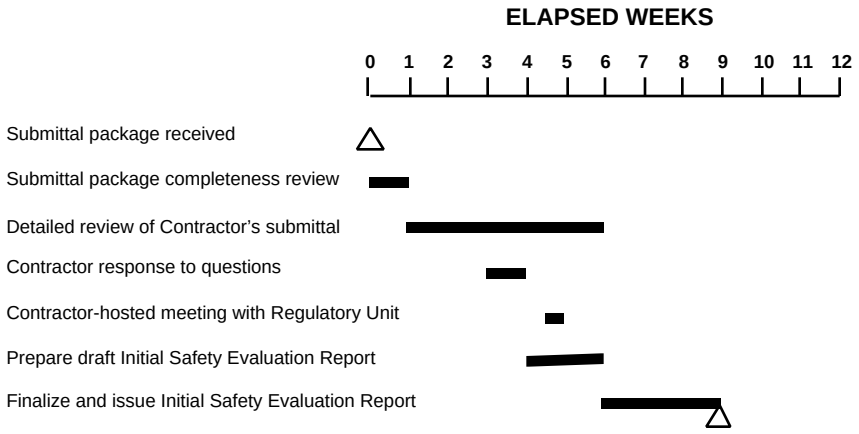

Figure 4. Reference Schedule for the Initial Safety Review.

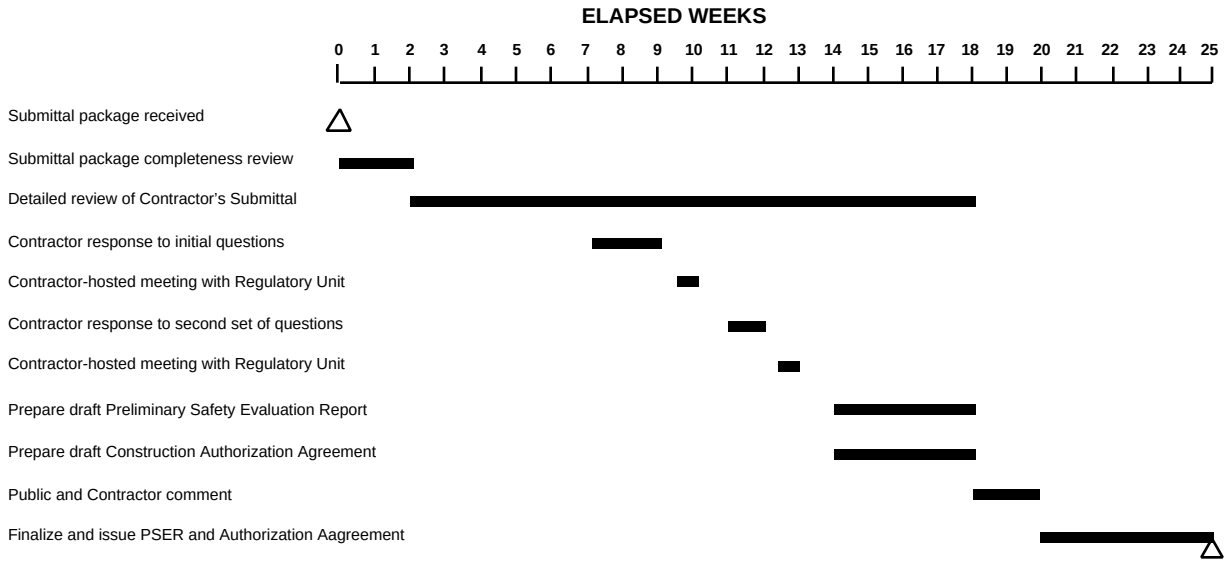

Figure 5. Reference Schedule for Issuing a Construction Authorization.

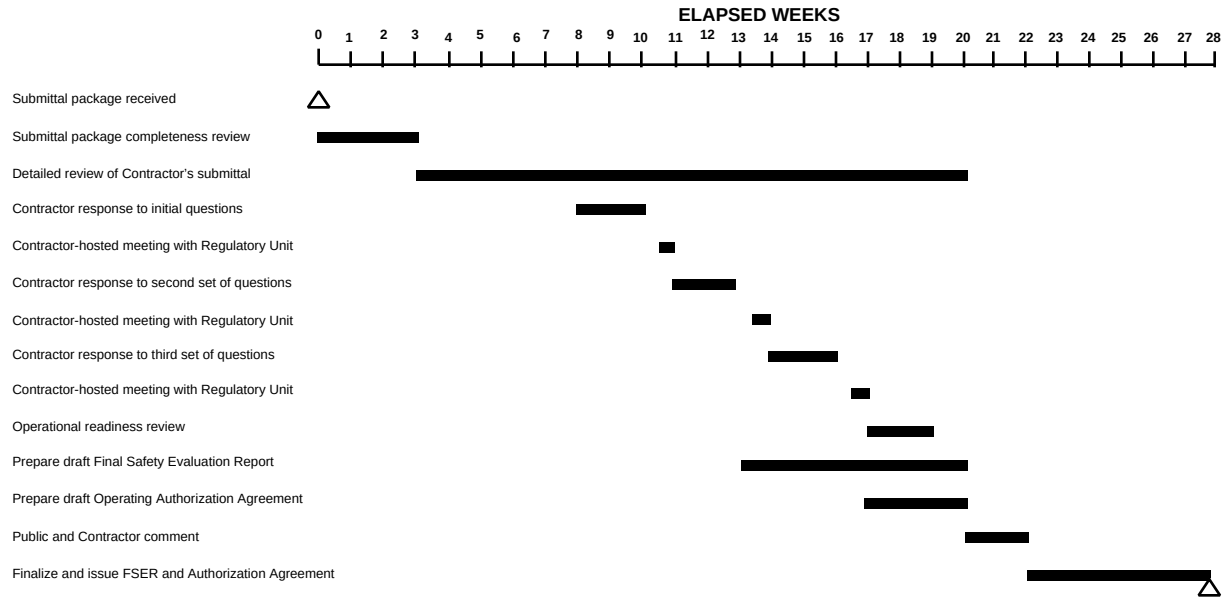

Figure 6. Reference Schedule for Issuing an Operating Authorization.

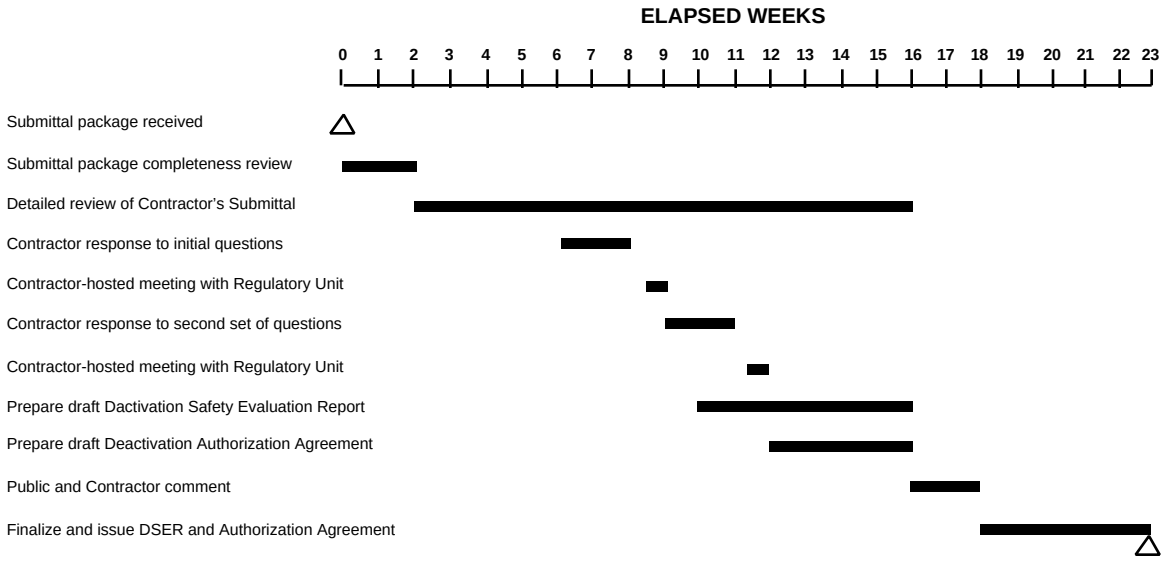

Figure 7. Reference Schedule for Issuing a Deactivation Authorization.

6.0 Glossary*

Acceptable Release. The release of radioactive material, within acceptable limits, to the environment.

Anticipated Operational Occurrences. Conditions of normal operation expected to occur one or more times during the life of the facility and include, but are not limited to, loss of off-site power to the process activity within the facility.

Authorization Agreement. The document mutually agreed upon by the Director of the Regulatory Unit and a regulated Contractor that specifies authorization terms and conditions.

Authorization Basis. The composite of information provided by a Contractor in response to radiological, nuclear, and process safety requirements that is the basis on which the Director of the Regulatory Unit grants permission to perform regulated activities.

Back-fit. The addition, elimination, or modification of 1) structures, systems, or components of the facility or 2) procedures or organizations required to operate the facility after the operating authorization has been issued.

Catastrophic Release. A major uncontrolled emission, fire, or explosion involving one or more highly hazardous chemicals that presents serious danger to employees in the workplace.

Co-located Worker. An individual within the Hanford Site, beyond the Contractor-controlled area, performing work for or in conjunction with DOE or utilizing other Hanford Site facilities.

Common-Cause Failures. Dependent failures that are caused by a condition external to a system or set of components that make system or multiple component failures more probable than multiple independent failures.

Common-Mode Failures. Dependent failures caused by susceptibilities inherent in certain systems or components that make their failures more probable than multiple independent failures due to those components having the same design or design conditions that would result in the same level of degradation.

Contractor(s). The private company(ies) selected to contract with DOE for construction and operation of the technologies and facilities necessary to retrieve, process tank waste, and deliver treated waste products to DOE for storage or disposal.

Contractor Representative (CR). The top manager of the Contractor Organization that has direct responsibility, accountability, and authority for performing the TWRS Privatization work subject to the set of standards.

Contractor-recommended set of standards and requirements. Those standards and requirements identified through a DOE-specified process and recommended by the Contractor Representative as necessary assurance that work will be performed in a manner that protects the workers, the public, and the environment from the actual hazards identified for the Contractor's specific work activities. (Also see the definition for "Requirements.") The recommended set serves as a basis for DOE review and approval by the Director of the Regulatory Unit, and the Contractor’s issuance of the Safety Requirements Document.

Controlled Area. The physical area enclosing the facility by a common perimeter (security fence). Access to this area can be controlled by the Contractor. The controlled area may include identified restricted areas.

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* Certain terms used in this document and listed in this glossary have origins in radiological and nuclear safety. Extension of their use to process safety may be useful but is not stipulated herein. It is expected that the extension of their use to process safety will be considered as part of the standards and requirements identification process.

Deactivation Safety Evaluation Report. The document approved and issued by the Director of the Regulatory Unit that addresses the adequacy of the authorization basis for deactivation.

Defense in Depth. The fundamental principle underlying the safety technology of the facility centered on several levels of protection including successive barriers preventing the release of radioactive materials to the workplace or environment. Human aspects of defense in depth are considered to protect the integrity of the barriers, such as quality assurance, administrative controls, safety reviews, operating limits, personnel qualification and training, and safety program. Design provisions, including both those for normal facility systems and those for systems important to safety help to: 1) prevent undue challenges to the integrity of the physical barriers; 2) prevent failure of a barrier if it is challenged; 3) where it exists, prevent consequential damage to multiple barriers in series; and 4) mitigate the consequences of accidents. Defense in depth helps to assure that two basic safety functions (controlling the process flow and confining the radioactive material) are preserved and that radioactive materials do not reach the worker, public, or the environment.

Design Basis. The information that identifies the specific functions to be performed by structures, systems, or components of the facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

Design-Basis Events. Postulated events providing bounding conditions for establishing the performance requirements of structures, systems, and components that are necessary to: 1) ensure the integrity of the safety boundaries protecting the worker; 2) place and maintain the facility in a safe state indefinitely; or 3) prevent or mitigate the event consequences so that the radiological exposures to the general public or the workers would not exceed appropriate limits. The Design-Basis Events also establish the performance requirements of the structures, systems and components whose failure under Design-Basis Event conditions could adversely affect any of the above functions.

Director of the Regulatory Unit (DRU). An individual who has been delegated the authority to execute the radiological, nuclear, and process safety regulation of TWRS Privatization Contractors.

DOE-Customer. A DOE employee who has knowledge of the equipment, facilities, and processes necessary for performance by the Contractor of the work activities to deliver the contracted services.

ESH Standards Experts (ESE). Individuals with knowledge and expertise relevant to the radiological, nuclear, or process standards and requirements in a particular environment, safety, and health discipline.

Facility. Those buildings and equipment directed to a common purpose and those activities and supporting elements occurring at a single location.

Final Safety Evaluation Report. The document approved and issued by the Director of the Regulatory Unit that addresses the adequacy of the authorization basis for operation.

Hazard. A source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to personnel, damage to an operation, or to the environment (without regard for the likelihood or credibility of accident scenarios or consequence mitigation).

Hazards Assessment Experts (HAE). Individuals with the knowledge, skills and abilities to identify, based on examination of the work activities defined, the hazards associated with the work activities, as well as the risk to the workers, public and environment attributable to those hazards.

Hazards Control Experts (HCE). Individuals with knowledge, skills and abilities to identify, based on examination of the work activities and associated hazards, the controls necessary to mitigate the hazards to an acceptable level.

Highly Hazardous Chemical. A substance possessing toxic, reactive, flammable, or explosive properties as defined by 29 CFR 1910.119.

Important to Safety. Structures, systems, and components that serve to provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the workers and the public. It encompasses the broad class of facility features addressed (not necessarily explicitly) in the top-level radiological, nuclear, and process safety standards and principles that contribute to the safe operation and protection of workers and the public during all phases and aspects of facility operations (i.e., normal operation as well as accident mitigation).

This definition includes not only those structures, systems, and components that perform safety functions and traditionally have been classified as safety class, safety-related or safety-grade, but also those that place frequent demands on or adversely affect the performance of safety functions if they fail or malfunction, i.e., support systems, subsystems, or components. Thus, these latter structures, systems, and components would be subject to applicable top-level radiological, nuclear, and process safety standards and principles to a degree commensurate with their contribution to risk. In applying this definition, it is recognized that during the early stages of the design effort all significant systems interactions may not be identified and only the traditional interpretation of important to safety, i.e., safety-related may be practical. However, as the design matures and results from risk assessments identify vulnerabilities resulting from non-safety-related equipment, additional structures, systems, and components should be considered for inclusion within this definition.

Independent Oversight. Authorized oversight by bodies or groups having no financial, programmatic, or other direct interest in the activities or organizations under review and which are totally free of management relationships with those activities or organizations.

Independent Oversight Bodies. Independent Oversight Bodies are those established organizations that have no financial, programmatic, or other direct interest in and are outside the management structure of the Contractor and the Regulatory Unit. The independent oversight bodies include personnel qualified and skilled to critique, evaluate, and recommend that the regulatory oversight provided by the Regulatory Unit of the Contractor is effective.

Independent Review Team (IRT). A group of individuals with the appropriate knowledge and expertise to review the recommended standards set for completeness, credibility, and adequacy before the standards are recommended by the Contractor Representative to the Director of the Regulatory Unit.

Initial Safety Evaluation Report. The document, approved and issued by the Director of the Regulatory Unit, that addresses the capability or potential for obtaining future authorizations for construction, operation, and deactivation.

Integrated Safety Management Plan (ISMP) Evaluation Report. The document, approved and issued by the Director of the Regulatory Unit, that addresses the adequacy of the Contractor's Integrated Safety Management Program as reflected in its Integrated Safety Management Plan.

Integrated Safety Management Program. A set of integrated activities that is directed toward the management or control of radiological, nuclear, and process hazards such that adequate protection is provided to workers, the public, and the environment.

Limiting Conditions for Operations (LCO). The lowest functional capability or performance level of equipment required for safe operation of the facility.

Limiting Control Settings (LCS). The settings for automatic alarm or protection devices related to those variables having significant safety functions.

Margin of Safety. The level of confidence that is assigned to the integrity of radiological control measures such as confinement barriers. It is defined as the range between the design acceptance limits and the design failure point of the control feature. The design acceptance limits for radiological control measures such as confinement barriers are established during the design of the facility. These criteria are given in terms of those physical parameters that define their performance. Whenever the values of the design acceptance limits are exceeded, the margin of safety, and therefore the confidence in the integrity of the control feature, is decreased.

Normal Operation. Steady-state operation and those departures from steady-state operation that are expected frequently or regularly in the course of facility operation, system testing, and maintenance. It includes conditions such as startup, shutdown, standby, anticipated operational occurrences, operation with specific equipment out of service as permitted by the approved operational constraints, and routine inspection, testing, and maintenance of components and systems during any of these conditions if it is consistent with the approved operational constraints.

Off-site. The area outside the perimeter of the Hanford Site.

On-site. The area within the Hanford Site control perimeter, which is under the jurisdiction of DOE.

Oversight Safety Determination. The oversight of the Contractors performed by the Regulatory Unit to ensure continuing compliance to an authorization agreement.

Postulated Accidents. Events, including the design-basis events, that would have an adverse affect on the facility process but which do not have a significant probability of occurrence during the life of the facility and include, but are not limited to, pipe or tank failures.

Preliminary Safety Evaluation Report. The document, approved and issued by the Director of the Regulatory Unit, that addresses the adequacy of the authorization basis for construction.

Process. Any activity involving a highly hazardous chemical including use, storage, manufacturing, handling, or the on-site movement of such chemicals, or a combination of these activities.

Process Manager (PM). A person, designated by the Contractor Representative, responsible for ensuring that the Process Steps are accomplished.

Process Management Team (PMT). A group of individuals designated by the Contractor Representative to approve specified actions proposed by the Process Manager and to monitor their implementation.

Process Safety. The operation of facilities that handle, use, process, or store hazardous materials in a manner free of episodic or catastrophic incidents. However, the handling, use, processing, and storage of materials with inherent hazardous properties can never be done in the total absence of risk. Process safety is an ideal condition towards which one strives.

Process Safety Management. The application of management systems to the identification, understanding, and control of process hazards to prevent process-related injuries and incidents.

Public. Individuals who are not occupationally engaged at the Hanford Site.

Radiation Worker. A worker who has qualifications and training to work in a restricted area of the facility where radiation or radioactive material is present.

Regulatory Unit. The organization reporting to the Director of the Regulatory Unit dedicated to supporting the Director in executing regulatory authority.

Reliability Targets. Quantified probabilistic expectations that a component, equipment, or system will perform its intended function satisfactorily under given circumstances, such as environmental conditions, limitations as to operation time, and frequency and thoroughness of maintenance for a specified period of time. Identified important to safety items are expected to perform their function satisfactorily through all design basis accident conditions.

Requirements. Standards that are mandated by an authority through statute, regulation, or contract.

Restricted Area. An area identified by the Contractor to which access is limited for the purposes of protecting individuals against undue risk from exposure to radiation and radioactive materials. Only a radiation worker is allowed into this area.

Risk Analysis. The development of a qualitative or quantitative estimate of risk based on engineering evaluation and techniques for considering estimates of incident consequences and frequency.

Safe State. A situation in which the facility process has been rendered safe and no pressurized material flow occurs in the process lines. Any active, energy generating, process reactions are in controlled or passive equipment. The structures, systems, and components necessary to reach and maintain this condition are functioning in a stable manner, with all process parameters within normal safe state ranges.

Safety Analysis Report (SAR). A document that fully describes the analyzed safety basis for the facility (safety envelope), fully demonstrates that the facility will perform and will be operated such that radiological, nuclear, and process safety requirements are met, and fully demonstrates adequate protection of the public, the workers, and the environment.

Safety Assurance. Established confidence that adequate protection of worker and public health and safety has been provided.

Safety Basis. The combination of information relating to the control of hazards at a nuclear facility (including design, engineering analyses, and administrative controls) upon which the Director of the Regulatory Unit depends for its conclusion that activities at the facility can be conducted safely.

Safety Function. Any function that is necessary to ensure: 1) the integrity of the boundaries retaining the radioactive materials; 2) the capability to place and maintain the facility in a safe state; or 3) the capability to prevent or mitigate the consequences of facility conditions that could result in radiological exposures to the general public or workers in excess of appropriate limits.

Safety Limits. Limits on process variables associated with those physical barriers, generally passive, that are necessary for the intended facility safety functions and that are found to be required to prevent release of unacceptable levels of radioactive material to workers or the general public.

Safety Requirements Document (SRD). A document that contains the approved and mandated set of radiological, nuclear, and process safety standards and requirements which, if implemented, provides adequate protection of workers, the public, and the environment against the hazards associated with the operation of the Contractor's facilities.

Safety Requirements Document Evaluation Report. The document approved and issued by the Director of the Regulatory Unit that addresses the adequacy of the set of radiological, nuclear, and process safety standards that a Contractor proposes to implement to ensure adequate protection of worker and public health and safety.

Safety Setpoints. Physical parameters set in the control equipment by an operator for equipment that controls the process or process flow to maintain the process within the systems design safety limits. A safety set-point represents a process characteristic, such as pressure, temperature, or material level, that is monitored by a control system to restrict the process characteristic within a system's design operating range. These set-points, identified in the design as levels above which a process physical parameter would exceed a design operating range of a process component or system leading to its failure and risk to the safety of the worker, public, or the environment. Several may be used to initiate alarm levels or control the process to a safe state.

Significantly New Safety Information. Either: 1) a safety requirement newly mandated by the Regulatory Unit; 2) a safety item newly identified by the Contractor as an item not included in the SAR for the facility; or 3) a determination that an unresolved safety question exists.

Stakeholder. Any individual other than Federal employees or DOE contractor employees that will be materially affected by, or can materially affect, the outcome of the work, either favorably or unfavorably.

Standards. The expressed expectation for the performance of work.

State-of-the-Art Human Factors. The most effective design approaches established for use at the start of the final design phase.

Technical Safety Requirements. Those requirements that define the conditions, the safe boundaries, and the management or administrative controls necessary to ensure the safe operation of the facility, reduce the potential risk to the public and facility workers from uncontrolled releases of radioactive materials, and from radiation exposures due to inadvertent criticality.

Unreviewed Safety Question (USQ). A safety question where any of the following conditions are satisfied: 1) the probability of occurrence or the radiological consequences of an accident or malfunction of equipment important to safety, previously evaluated in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility analysis, may be increased; 2) a possibility for an accident or equipment malfunction of a different type than any evaluated previously in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility safety analysis, may be created; or 3) any margin of safety is reduced. (Also see definition for "Margin of Safety.")

Worker. Worker means an individual within the controlled area of the facility performing work for or in conjunction with the Contractor or utilizing Contractor facilities.

Work Activities. All activities associated with performing the work, including design, construction, operation, and deactivation.

Work Activity Experts. Individuals with knowledge and expertise relevant to the work, site, and activities addressed by the standards set.